ISRCTN88015476 https://doi.org/10.1186/ISRCTN88015476

Randomised trial of reamed versus non-reamed nails in tibial fractures

Submission date	Recruitment status
29/06/2004	No longer recruiting
Registration date	**Overall study status**
22/07/2004	Completed
Last Edited	**Condition category**
30/01/2019	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sprint-trial.com/index.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00038129

Secondary identifying numbers
MCT-38140

Study information

Scientific Title
Randomised trial of reamed versus non-reamed nails in tibial fractures

Acronym
SPRINT

Study objectives
Our primary objective is to assess the impact of reamed versus non-reamed intramedullary nailing on rates of re-operation (including bone grafts, operation for infection, dynamisation; removal of locking screw(s) due to hardware breakage or loosening of screws, and fasciotomy for intra-operative or post-operative compartment syndrome) in patients with 50% or greater cortical continuity, or less than 1 cm gap between the fracture ends post intramedullary nailing.

Our secondary objective is to assess the impact of reamed and non-reamed intramedullary nailing on functional status, quality of life, and return to normal activities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of McMaster University, Hamilton, Ontario (Canada) on the 20th April 1999 (ref: # 99-077).

Study design
Multicentre, international, two arm, randomised parallel surgical trial with data analyst blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tibial shaft fractures

Interventions

Reamed Nail Insertion:
Reaming is conducted over the guide wire with cannulated power reamers. The attending surgeon chooses the reamer. To avoid inconsistencies in the degree of reaming, surgeons adhere to the following protocol:
1. Surgeons ream the intramedullary canal until the first detection of "cortical chatter" (i.e. the reamer just begins to contact the cortical bone of the tibia)
2. The size of the nail (diameter) corresponds to the point of "cortical chatter" (if chatter occurs with a 11 mm reamer, then the nail size is 11 mm
3. Following the appearance of "cortical chatter" surgeons ream 1 - 1.5 mm larger than the chosen nails diameter to facilitate its insertion

The chosen nail, which is as long as possible without distracting the fracture by impinging on dense distal metaphyseal bone or protruding above the cortex at the insertion site, is inserted with the appropriate instruments. Distraction of a tibial shaft fracture interferes with healing, so surgeons employ all strategies for achieving cortical contact (up to 10 mm shortening acceptable to achieve contact of fracture ends). The choice of intramedullary nail manufacturer and material (titanium or stainless steel) is at the discretion of the operating surgeon.

Non-Reamed Nail Insertion:
Surgeons insert non-reamed nails across the fracture site ensuring minimal distraction. The goal is to achieve cortical contact of the fracture ends. An upper diameter limit of 10 mm is employed for non-reamed nails. However, in principle the nail should be at least 2 mm less than the diameter at the isthmus of the tibia on anteroposterior and lateral radiographs.

For further information, please contact Dr Bhandari at the address listed below or the principal investigator Dr Gordon Guyatt.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Impact of reamed and nonreamed intramedullary nailing on:
1. Rates of re-operation
2. Rates of complications

Secondary outcome measures
Functional status using:
1. The Health Utilities Index
2. 36-item Short-Form health survey
3. Tibia Knee Pain Questionnaire
4. The Short Musculoskeletal Functional Assessment

Overall study start date
01/01/2000

Completion date
30/03/2007

Eligibility

Key inclusion criteria
1. 900 patients of either sex
2. Aged 18 and over
3. With a sustained tibial fracture that requires an operative treatment
4. In 10 Canadian and 13 US centres

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
900

Key exclusion criteria
1. Fractures not amenable to intramedullary nailing (less than 5 cm distal to the tibial tubercle, or less than 5 cm proximal to the tibiotalar joint)
2. Inability to pass a non-reamed nail
3. Fractures with associated neurovascular deficits (Gustillo Grade IIIC injuries)
4. Pathologic fractures
5. Surgical delay of greater than 12 hours from time of injury (open fractures)
6. Surgical delay of greater than 3 weeks from time of injury (closed fractures)
7. Retained hardware in the affected limb that would interfere with intramedullary nailing
8. Associated fractures of the foot, ankle, or knee
9. Likely problems, in the judgment of the investigators, with maintaining follow-up. For example, we will exclude patients with no fixed address, those who report a plan to move out of town in the next year, or intellectually challenged patients without adequate family support

Date of first enrolment
01/01/2000

Date of final enrolment
30/03/2007

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
McMaster University
Hamilton, ON
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Sponsor information

Organisation
McMaster University (Canada)

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Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-38140)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/06/2008	30/01/2019	Yes	No
Results article	results	01/06/2012	30/01/2019	Yes	No
Results article	results	01/11/2009	30/01/2019	Yes	No
Results article	results	01/06/2011	30/01/2019	Yes	No
Results article	results	01/09/2016	30/01/2019	Yes	No